The following information is provided as guidance for all Surgery Centers that are utilizing a Practitioner Registration as the DEA# by which they order in all controlled substances to be utilized within the facility. Per DEA Regulations all Surgery Centers are considered to be Hospital/Clinics and should be registered as such.

In the effort to convert all Mississippi Surgery Centers from utilizing a Business Activity: Practitioner DEA Registration to Business Activity: Hospital/Clinic DEA Registration, each location will need to apply for a DEA Registration as a Hospital/Clinic.

1 - Business Activity: Hospital/Clinic

According to how the business is registered with the MS Secretary of State (the owners, partners and/or corporate officers should be listed here) will be how the applicant shall proceed.

- If sole ownership, it will be treated as an individual;
- Partnership (any one of the partners may apply) and;
- Corporation (any corporate officer may apply).

The applicant will go to the DEA website, *www.DEAdiversion.usdoj.gov*, and fill out a new DEA Form 224 application for registration as a Hospital/Clinic (business activity). Please ensure that when applying for the new registration you check "Yes" to needing DEA Form 222's to purchase Schedule I and II from suppliers.

Once the application is processed the applicant can create a power of attorney for whomever they choose to be their representative to order controlled substances, complete DEA Form 222s or Controlled Substance Ordering System (CSOS) on their behalf.

The following are excerpts from Title 21 Code of Federal Regulations (CFR) 1300. If you need further guidance please refer to the CFR and the Pharmacist Manual as found on the Diversion website *www.DEAdiversion.usdoj.gov* under Resources and Publications & Manuals, respectively.

1301.13 Application for registration; time for application; expiration date; registration for independent activities; application forms, fees, contents and signature; coincident activities.

(a) – (i) – Intentionally Removed

(j) Each application, attachment, or other document filed as part of an application, shall be signed by the applicant, if an individual; by a partner of the applicant, if a partnership; or by an officer of the applicant, if a corporation, corporate division, association, trust or other entity. An applicant may authorize one or more individuals, who would not otherwise be authorized to do so, to sign applications for the applicant by filing with the Registration Unit of the Administration a power of attorney for each such individual. The power of attorney shall be signed by a person who is authorized to sign applications under this paragraph and shall contain the signature of the individual being authorized to sign applications. The power of attorney shall be valid until revoked by the applicant.

1301.15 Additional information.

The Administrator may require an applicant to submit such documents or written statements of fact relevant to the application as he/she deems necessary to determine whether the application should be granted. The failure of the applicant to provide such documents or statements within a reasonable time after being requested to do so shall be deemed to be a waiver by the applicant of an opportunity to present such documents or facts for consideration by the Administrator in granting or denying the application.

1301.91 Employee responsibility to report drug diversion.

Reports of drug diversion by fellow employees is not only a necessary part of an overall employee security program but also serves the public interest at large. It is, therefore, the position of DEA that an employee who has knowledge of drug diversion from his employer by a fellow employee has an obligation to report such information to a responsible security official of the employer. The employer shall treat such information as confidential and shall take all reasonable steps to protect the confidentiality of the information and the identity of the employee furnishing information. A failure to report information of drug diversion will be considered in determining the feasibility of continuing to allow an employee to work in a drug security area. The employer shall inform all employees concerning this policy.

1301.92 Illicit activities by employees.

It is the position of DEA that employees who possess, sell, use or divert controlled substances will subject themselves not only to State or Federal prosecution for any illicit activity, but shall also immediately become the subject of independent action regarding their continued employment. The employer will assess the seriousness of the employee's violation, the position of responsibility held by the employee, past record of employment, etc., in determining whether to suspend, transfer, terminate or take other action against the employee.

2 - Once the new application has been processed for the Hospital/Clinic and a new DEA# has been issued, the Medical Director will follow these steps to transfer and close out the current DEA# (practitioner DEA# the one currently being used for the Surgery Center):

- Take a Final Inventory;
  - Schedule II and III-V on separate inventories;
- Transfer all controlled substances from the practitioner DEA# to the Hospital/Clinic DEA#;
  - Schedule II - DEA Form 222;
  - Schedule III-V - Invoice;
  - These records will need to be retained by the practitioner for two years;

The Hospital/Clinic will follow these steps:

- Take an Initial Inventory (should be 0);
  - Schedule II and III-V on separate inventories;
- Receive all controlled substances from the practitioner DEA# to the Hospital/Clinic DEA#;
  - Schedule II - DEA Form 222;
  - Schedule III-V - Invoice;
  - These records will need to be retained by the hospital/clinic for two years.

1304.11 Inventory requirements.

(a) ***General requirements.*** Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and shall be maintained in written, typewritten, or printed form at the registered location. An inventory taken by use of an oral recording device must be promptly transcribed. Controlled substances shall be deemed to be "on hand" if they are in the possession of or under the control of the registrant, including substances returned by a customer, ordered by a customer but not yet invoiced, stored in a warehouse on behalf of the registrant, and substances in the possession of employees of the registrant and intended for distribution as complimentary samples. A separate inventory shall be made for each registered location and each independent activity registered, except as provided in paragraph (e)(4) of this section. In the event controlled substances in the possession or under the control of the registrant are stored at a location for which he/she is not registered, the substances shall be included in the inventory of the registered location to which they are subject to control or to which the person possessing the substance is responsible. The inventory may be taken either as of opening of business or as of the close of business on the inventory date and it shall be indicated on the inventory.

(b) ***Initial inventory date.*** Every person required to keep records shall take an inventory of all stocks of controlled substances on hand on the date he/she first engages in the manufacture,

distribution, or dispensing of controlled substances, in accordance with paragraph (e) of this section as applicable. In the event a person commences business with no controlled substances on hand, he/she shall record this fact as the initial inventory.

(c) ***Biennial inventory date.*** After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory may be taken on any date which is within two years of the previous biennial inventory date.

(d) ***Inventory date for newly controlled substances.*** On the effective date of a rule by the Administrator pursuant to §§ 1308.45, 1308.46, or 1308.47 of this chapter adding a substance to any schedule of controlled substances, which substance was, immediately prior to that date, not listed on any such schedule, every registrant required to keep records who possesses that substance shall take an inventory of all stocks of the substance on hand. Thereafter, such substance shall be included in each inventory made by the registrant pursuant to paragraph (c) of this section.

(e) ***Inventories of manufacturers, distributors, registrants that reverse distribute, importers, exporters, chemical analysts, dispensers, researchers, and collectors.*** Each person registered or authorized (by §§ 1301.13, 1307.11, 1307.13, or part 1317 of this chapter) to manufacture, distribute, reverse distribute, dispense, import, export, conduct research or chemical analysis with controlled substances, or collect controlled substances from ultimate users, and required to keep records pursuant to § 1304.03 shall include in the inventory the information listed below.

(1) Intentionally Removed

(i)-(ii) – Intentionally Removed

(iii) For each controlled substance in finished form the inventory shall include:

(A) The name of the substance;

(B) Each finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter);

(C) The number of units or volume of each finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial); and

(D) The number of commercial containers of each such finished form (e.g. four 100-tablet bottles or six 3-milliliter vials).

(iv) For each controlled substance not included in paragraphs (e)(1) (i), (ii) or (iii) of this section (e.g., damaged, defective or impure substances awaiting disposal, substances held for quality control purposes, or substances maintained for extemporaneous compoundings) the inventories shall include:

(A) The name of the substance;

(B) The total quantity of the substance to the nearest metric unit weight or the total number of units of finished form; and

(C) The reason for the substance being maintained by the registrant and whether such substance is capable of use in the manufacture of any controlled substance in finished form.

The Hospital/Clinic will be required to maintain records as required by 1300 CFR:

1304.21 General requirements for continuing records.

(a) Every registrant required to keep records pursuant to § 1304.03 shall maintain, on a current basis, a complete and accurate record of each substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of by him/her, and each inner liner, sealed inner liner, and unused and returned mail-back package, except that no registrant shall be required to maintain a perpetual inventory.

(b) Separate records shall be maintained by a registrant for each registered location except as provided in § 1304.04 (a). In the event controlled substances are in the possession or under the control of a registrant at a location for which he is not registered, the substances shall be included in the records of the registered location to which they are subject to control or to which the person possessing the substance is responsible.

(c) Separate records shall be maintained by a registrant for each independent activity and collection activity for which he/she is registered or authorized, except as provided in § 1304.22(d).

(d) In recording dates of receipt, distribution, other transfers, or destruction, the date on which the controlled substances are actually received, distributed, otherwise transferred, or destroyed will be used as the date of receipt, distribution, transfer, or destruction (*e.g.*, invoices or packing slips, or DEA Form 41). In maintaining records concerning imports and exports, the registrant must record the anticipated date of release by a customs official for permit applications and declarations and the date on which the controlled substances are released by a customs officer at the port of entry or port of export for return information.

(e) ***Record of destruction.*** In addition to any other recordkeeping requirements, any registered person that destroys a controlled substance pursuant to § 1317.95(d), or causes the destruction of a controlled substance pursuant to § 1317.95(c), shall maintain a record of destruction on a DEA Form 41. The records shall be complete and accurate, and include the name and signature of the two employees who witnessed the destruction. Except, destruction of a controlled substance dispensed by a practitioner for immediate administration at the practitioner's registered location, when the substance is not fully exhausted (e.g., some of the substance remains in a vial, tube, or syringe after administration but cannot or may not be further

utilized), shall be properly recorded in accordance with § 1304.22(c), and such record need not be maintained on a DEA Form 41.

3 - Once all controlled substances have been transferred to the new Hospital/Clinic DEA# the practitioner may do one of the following with the DEA# that was being used as the primary registration for the surgery center:

- Retain the registration at the current location for prescribing only;
- Move the registration to a different practice location;
  - May be used to prescribe, order, store, administer or dispense controlled substances;
- Discontinue use of the registration;
  - Notifying DI Martin in writing at angela.c.martin@dea.gov of the desire to put the registration "out of business";
  - Send the following to the Drug Enforcement Administration, Jackson District Office, Attn: DI Martin; 100 West Capitol Street, STE 1100, Jackson, MS 39269:
    - DEA Certificate of Registration; and
    - Unexecuted / VOIDED, DEA Form 222s.

1301.52 Termination of registration, transfer of registration; distribution upon discontinuance of business.

(a) – (b) Intentionally Removed

(c) Any registrant desiring to discontinue business activities altogether or with respect to controlled substances (without transferring such business activities to another person) shall return for cancellation his/her certificate of registration, and any unexecuted order forms in his/her possession, to the Registration Unit, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address. Any controlled substances in his/her possession may be disposed of in accordance with part 1317 of this chapter.

(d) - (f) Intentionally Removed

For further guidance please refer to 21 Code of Federal Regulations 1300 and the Pharmacist Manual as found on the Diversion website *www.DEAdiversion.usdoj.gov* under Resources and Publications & Manuals, respectively. If you have any questions please feel free to reach out to DI Martin at 601-383-1057 or via email at angela.c.martin@dea.gov.